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Reconstructive

Ambulatory Status before Diabetic Foot Ulcer Development as a Predictor of Amputation and 1-Year Outcomes: A Retrospective Analysis

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Background: Up to 25% of people with diabetes develop a diabetic foot ulcer (DFU) during their lifetime, which precedes approximately 85% of nontraumatic lower limb amputations. Diabetic limb salvage has been at the forefront of recent research, as major amputation is associated with 5-year mortality rates of 52%–80%. We sought to determine if ambulatory status before DFU diagnosis is predictive of amputations and outcomes within 1 year, as no studies have directly examined this relationship.

Methods: A retrospective review of patients diagnosed with DFUs from January 2011 to December 2021 was performed. Patients aged 18 years or more with type II diabetes were included. Ambulatory status was defined as the primary form of mobility reported by the patient before development of DFU, and was categorized as independent ambulation, ambulatory with assisting device (AWAD), or non-ambulatory (NA). Statistical analyses included χ^2, multinomial, and multivariable logistic regressions.

Results: After review, 506 patients were included. NA (OR = 5.10; $P = 0.002$) and AWAD status (OR = 2.77; $P = 0.01$) before DFU development were predictive of major (below or above-knee) amputation during hospitalization, emergency department visits within 30-days (NA: OR = 4.19; $P = 0.01$, AWAD: OR = 3.09; $P = 0.02$), and mortality within one-year (NA: OR = 4.19; $P = 0.01$, AWAD: OR = 3.09; $P = 0.02$). AWAD status was also associated with increased risk of hospital readmission (OR = 2.89; $P < 0.001$) within 30-days and any amputation (OR = 1.73; $P = 0.01$) within 1 year.

Conclusions: In patients with DFUs, NA and AWAD status were predictive of major amputation during hospitalization and are associated with poorer 1-year outcomes, including mortality. Ambulatory status assessment may be used to inform DFU treatment approaches. *(Plast Reconstr Surg Glob Open 2023; 11:e5383; doi: 10.1097/GOX.0000000000005383; Published online 9 November 2023.)*

INTRODUCTION

An estimated 25% of people with diabetes will develop a diabetic foot ulcer (DFU) during their lifetime, with DFUs preceding 85% of nontraumatic lower-limb amputations.[1–5] People with diabetes are at higher risk of developing a nonhealing wound due to hyperglycemia, poor circulation, sedentary lifestyle, neuropathy, and compromised immunity, leading to microvascular and macrovascular damage.[3,6,7] As more than 11.3% of the US population currently has diabetes,[8] and an estimated 300 million people worldwide are expected to be diagnosed by 2025,[3] this represents a growing challenge.

Although peripheral neuropathy accounts for the highest incidence of microvascular complications, excessive plantar pressure due to limited joint-mobility and foot deformity contributes greatly to the majority of DFUs.[1–3,5] As neuropathy can directly lead to foot deformity and gait imbalance, this results in overall impairments in ambulation, further perpetuating the mechanical stress causing wounds.[5] DFU prevention guidelines strongly suggest screening for limited joint-mobility at regular intervals to decrease the likelihood of development, with foot

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and mobility-related exercises recommended for at-risk patients.[9]

Mortality following amputation ranges from 13% to 40% at 1 year and from 39% to 80% at 5 years, which is worse than most malignancies.[1,10,11] Although amputation is ideally followed by prosthesis use, many patients are unable to achieve this.[11–14] The implementation of multidisciplinary DLS services has led to decreased amputation rates and significant mortality benefit.[15–19] Studies have reported high rates of success, specifically with free tissue transfers, with improved postoperative functional status compared with amputations.[15,19–22] As amputation can have a significant impact on cardiovascular dynamics and energy expenditure, limb salvage may preserve quality of life and minimize the risk of deconditioning that leads to further morbidity and mortality.[3,17]

Despite the evidence that impaired mobility leads to DFU development, little has been reported on the relationship of ambulatory status before DFU development and patient outcomes. We sought to determine if ambulatory status before DFU development and diagnosis is predictive of amputations and outcomes within 1 year, to identify patients at higher risk for poor outcomes who may benefit most from limb salvage consideration.

Takeaways

Question: Is impaired patient ambulatory status before the development and diagnosis of diabetic foot ulcers predictive of amputation and outcomes within 1 year?

Findings: Nonambulatory and ambulatory with an assisting device statuses before diabetic foot ulcer (DFU) development were predictive of major amputation during initial hospitalization, emergency department visits within 30-days, and all-cause mortality within 1 year of DFU diagnosis.

Meaning: Impaired ambulation before DFU diagnosis predicted major amputation during initial hospitalization and poorer outcomes within 1 year. Ambulatory status assessment before DFU development may be used to inform DFU treatment approaches, including opportunity for DLS to improve outcomes.

METHODS

A retrospective review of all patients diagnosed with a DFU from January 2011 to December 2021 at a single tertiary-care institution was performed. Patients included were 18 years or older with type II diabetes, a foot ulcer not determined to be from other causes, and at least 1-year follow-up. This study was institutional review board–approved with waiver of informed consent requirement (University of Tennessee Graduate School of Medicine, Knoxville, Tenn.; IRB reference #4887). Amputation was defined as major (below or above-knee) or minor (toe or partial-foot). Ambulatory status was defined as the most used form of mobility reported by the patient before DFU development and diagnosis. Ambulatory status was categorized into three groups for analysis: independent ambulation (IA), ambulation with assisting devices (AWAD) such as a cane or walker, or nonambulatory (NA; wheelchair- or bedbound). As the etiology for patient ambulatory status was before the development of DFU, no patients were excluded for any specific causes (ie, NA due to paraplegia from prior trauma). “Amputation during hospitalization” was defined as amputation performed during the same hospital admission as initial DFU diagnosis. “Any lower extremity amputation within 1 year” was defined as amputation performed after discharge from initial hospitalization associated with DFU diagnosis within 1 year.

Chi-square analyses and Fisher exact tests were performed to compare independent groups on categorical outcomes, including initial bivariate associations between ambulatory status and amputation. Independent samples *t* tests were performed to test for differences between groups on continuous variables. Multinomial logistic regression analyses were performed to determine how a vector coded ambulation status (IA served as the reference category) is linked to major, minor, or no amputation during hospitalization after DFU diagnosis. Multivariable logistic regression analyses predicting hospital readmission and emergency department (ED) visits within 30 days, and all-cause mortality and lower extremity amputations within 1 year, were performed with the same vector coded ambulatory statuses. Covariates for multinomial and multivariable logistic regression analyses included sex, BMI, race, age, current smoking status, history of amputations, hypertension, number of diabetic foot wounds on presentation, stage of chronic renal failure (CRF) on presentation, congestive heart failure (CHF) diagnosis, history of foot ulcers, and history of vascular interventions. Odds ratios with confidence intervals were reported for the outcomes of interest, but parameter estimates for all covariates were not reported to ease interpretation. To compare parameter estimates of the two vector coded variables, Wald tests of parameter constraints were performed and reported between the impaired ambulatory statuses in each model. Statistical significance was assumed at an alpha value of 0.05.

RESULTS

After review of 1800 records, 506 patients met criteria for inclusion in this study. Of these, 243 (48.0%) reported IA, 175 (34.6%) reported AWAD, and 88 (17.4%) reported NA status before development and diagnosis of DFU. The average age of the study population was 62.9 years, with 61.0% men, an average body mass index (BMI) of 32.4 kg per m^2, and 88.3% identifying as White (Table 1). The NA group was significantly older, more often women, had the lowest average BMI, had a higher stage of CRF on presentation, more often had CHF, had a history of DFU, had previous vascular intervention, and more often died within one-year when compared with the other groups (Table 1). There were no significant differences in race, smoking status, previous amputations, hypertension, or number of DFUs diagnosed on presentation (Table 1).

Of the 506 patients included, 43 (8.5%) patients underwent major amputation, 117 (23.1%) underwent minor

Table 1. Description of Total Study and Ambulatory Status Groups

Variable	Study Population (*N* = 506)	Independent Ambulation (*n* = 243)	Nonambulatory (*n* = 88)	AWAD (*n* = 175)	*P*
Age (y)*	62.9 (12.0)	58.9 (10.9)	69.6 (11.5)	65.1 (11.6)	**<0.001**
Sex					
Male	311 (61.0%)	166 (68.3%)	41 (46.6%)	104 (59.4%)	
Female	195 (39.0%)	77 (31.7%)	47 (53.4%)	71 (40.6%)	**0.001**
Body mass index (kg/m^2)*	32.4 (8.0)	33.7 (7.3)	30.6 (7.7)	31.5 (8.8)	**0.003**
Race					
White	447 (88.3%)	212 (87.2%)	78 (88.6%)	157 (89.7%)	
Other	59 (11.7%)	31 (12.8%)	10 (11.4%)	18 (10.3%)	0.72
Current smoker					
Yes	120 (23.7%)	58 (23.9%)	17 (19.3%)	45 (25.7%)	0.55
Previous amputation					
Yes	133 (26.3%)	54 (22.2%)	30 (34.1%)	49 (28.0%)	0.08
Hypertension					
Yes	415 (82.0%)	193 (79.4%)	75 (85.2%)	147 (84.0%)	0.44
No. diabetic foot wounds*	1.4 (0.8)	1.4 (0.8)	1.5 (0.9)	1.4 (0.8)	0.44
Stage of chronic renal failure*	3.2 (1.9)	2.9 (1.9)	3.9 (1.7)	3.0 (1.9)	**0.01**
Congestive heart failure					
Yes	86 (17.0%)	22 (9.1%)	29 (33.0%)	35 (20.0%)	**<0.001**
Previous foot ulcers					
Yes	224 (44.3%)	95 (39.0%)	49 (55.7%)	80 (45.7%)	**0.03**
Previous vascular intervention					
Yes	149 (29.4%)	54 (22.2%)	33 (37.5%)	62 (35.4%)	**0.004**
Mortality within 1 year					
Yes	41 (8.1%)	7 (2.9%)	15 (17.0%)	19 (10.9%)	**<0.001**

Outcomes reported as total number within total study population and ambulation groups (percentage). Boldface indicates statistical significance, $P < 0.05$.
*Denotes outcome reported as mean (SD).

amputation, and 346 (68.4%) did not undergo any amputation during hospitalization after DFU diagnosis (Table 2). The proportion of NA patients who underwent major amputation was significantly higher than the other groups during initial hospitalization for DFU presentation (14.0% NA versus 10.3% AWAD versus 5.0% IA; $P = 0.006$). The proportion of NA patients receiving a minor amputation during hospitalization was significantly lower than the other groups (12.5% NA versus 23.4% AWAD versus 26.7% IA; $P = 0.006$).

Multinomial logistic regression analyses were performed to compare NA and AWAD status to IA in predicting major or minor amputation during hospitalization after DFU diagnosis while controlling for age, sex, race, and multiple comorbidities (Table 3). NA status before DFU diagnosis was associated with a 410% increase in the odds of undergoing major amputation during initial hospitalization (OR = 5.10, 95% CI 1.79–14.46; $P = 0.002$), whereas AWAD status was associated with a 177% increase in odds (OR = 2.77, 95% CI 1.25–7.28; $P = 0.01$). NA and AWAD status were not significantly associated with minor amputation during hospitalization.

Multivariable logistic regression analyses were performed for predicting 30-day and 1-year outcomes after DFU diagnosis while controlling for the same covariates (Table 4). AWAD status was significantly associated with a 189% increase in the odds of hospital readmission within 30-days (OR = 2.89, 95% CI 1.63–5.12; $P < 0.001$), whereas NA status was not. When examining the odds of re-presenting to the ED within 30 days, NA status was significantly associated with a 319% increase (OR = 4.19, 95% CI 1.52-11.63; $P = 0.01$), and AWAD status was significantly associated with a 209% increase (OR = 3.09, 95% CI 1.21–7.87; $P = 0.02$). When predicting any lower extremity amputation performed within 1 year of DFU diagnosis after initial hospitalization, AWAD status was significantly associated with a 73% increase in odds (OR = 1.73, 95% CI 1.13-2.72; $P = 0.01$) and NA status was not significantly associated. When predicting all-cause mortality within 1 year, NA status was associated with a 319% increase in odds (OR = 4.19, 95% CI 1.51–11.63; $P = 0.01$), and AWAD status was associated with a 209% increase in odds (OR = 3.09, 95% CI 1.21–7.87; $P = 0.02$).

DISCUSSION

Although ambulatory status before DFU development and diagnosis may be routinely considered by treatment

Table 2. Comparison of Ambulatory Status before the Development of DFUs and Amputations during Hospitalization

Variable	Study Population (*N* = 506)	IA (*n* = 243)	Nonambulatory (*n* = 88)	AWAD (*n* = 175)	*P*
Major amputation	43 (8.5%)	12 (5.0%)	13 (14.0%)	18 (10.3%)	
Minor amputation	117 (23.1%)	65 (26.7%)	11 (12.5%)	41 (23.4%)	
No amputation	346 (68.4%)	166 (68.3%)	64 (73.5%)	116 (66.3%)	**0.006**

Outcomes reported as total number within study population and ambulation groups (percentage). Bold indicates statistical significance, $P < 0.05$.

Table 3. Multinomial Logistic Regression Analyses Comparing Impaired Ambulatory Statuses to IA Predicting for Major or Minor Amputation during Hospitalization after DFU Diagnosis

	Major Amputation (n = 43)				Minor Amputation (n = 117)			
	*χ^2 (1) = 0.91, P = 0.34				*χ^2 (1) = 2.39, P = 0.12			
Variable	B (SE)	Odds Ratio	95% CI	P	B (SE)	Odds Ratio	95% CI	P
Nonambulatory*	1.63 (0.53)	5.10	1.79–14.46	**0.002**	–0.55 (0.38)	0.58	0.27–1.21	0.14
Ambulatory with assisting device*	1.02 (0.45)	2.77	1.25–7.28	**0.01**	0.004 (0.24)	1.01	0.62–1.62	0.99

Parameter estimates for all covariates were removed to ease interpretation. IA as reference group among ambulatory statuses. Bold indicates statistical significance, $P < 0.05$.

*Denotes Wald Test of Parameter Constraints between nonambulatory status and ambulation with assisting device. $P < 0.05$ indicates that you can reject the null hypothesis that the two parameters are equal. Therefore, $P > 0.05$ indicates that the two parameters are statistically equal.

Table 4. Multivariable Logistic Regression Analyses Comparing Impaired Ambulatory Statuses to IA for 30-Day and 1-Year Outcomes after DFU Diagnosis

	Hospital Readmission within 30 Days (N = 506)			
	*χ^2 (1) = 3.60, P = 0.06			
Variable	B (SE)	Odds Ratio	95% CI	P
Nonambulatory*	0.34 (0.42)	1.41	0.61–3.24	0.42
Ambulatory with assisting device*	1.06 (0.29)	2.89	1.63–5.12	**<0.001**
	Emergency Department Visit within 30 Days (N = 506)			
	*χ^2 (1) = 0.28, P = 0.60			
	B (SE)	**Odds ratio**	**95% CI**	**P**
Nonambulatory*	1.43 (0.52)	4.19	1.52–11.63	**0.01**
Ambulatory with assisting device*	1.13 (0.48)	3.09	1.21–7.87	**0.02**
	Any Lower Extremity Amputation within 1 Year (N = 506)			
	*χ^2 (1) = 2.50, P = 0.22			
	B (SE)	**Odds Ratio**	**95% CI**	**P**
Nonambulatory*	0.19 (0.30)	1.21	0.66–2.18	0.53
Ambulatory with assisting device*	0.55 (0.22)	1.73	1.13–2.72	**0.01**
	All-Cause Mortality within 1 Year (N = 506)			
	*χ^2 (1) = 0.60, P = 0.44			
	B (SE)	**Odds Ratio**	**95% CI**	**P**
Nonambulatory*	1.43 (0.52)	4.19	1.51–11.63	**0.01**
Ambulatory with assisting device*	1.13 (0.48)	3.09	1.21–7.87	**0.02**

Parameter estimates for all covariates were removed to ease interpretation. All odds ratios are expressed as predictors of outcome variables 30 days or 1 year after DFU diagnosis. IA as reference group among ambulatory statuses. Bold indicates statistical significance, $P < 0.05$.

*Denotes Wald Test of Parameter Constraints between nonambulatory status and ambulation with assisting-device. $P < 0.05$ indicates that you can reject the null hypothesis that the two parameters are equal. Therefore, $P > 0.05$ indicates that the two parameters are statistically equal.

teams, no studies have directly examined this relationship with amputation and outcomes within 1 year of diagnosis. The assessment of ambulatory status before DFU development may allow treatment teams to identify patients who are at higher risk for poor outcomes, with further consideration given for DLS to reduce the risk of major amputations and mortality.

Patients who were NA before diagnosis of DFU were significantly older, more often women, had the lowest average BMI, had higher stages of CRF, more often had CHF, had a history of foot ulcers, had previous vascular interventions, and more often died within 1 year when compared with the other ambulatory groups. Known risk factors for the development of DFU include older age, malnutrition, previous foot ulcers, and prior lower-extremity amputations.[1,6] These factors were most prevalent in the NA group, and may have contributed to their initial DFU development and poorer overall health status.

Among the study population, 8.5% of patients underwent major amputation, whereas 23.1% underwent minor amputation. The rate of major amputation was significantly higher in the NA group at 14.0%, whereas the rate of minor amputation was significantly higher in the IA group at 26.7% (Fig. 1).

Our findings indicate that impaired ambulatory status before DFU diagnosis is predictive of major amputation during initial hospitalization. NA and AWAD status significantly increased the odds of undergoing major amputation during initial hospitalization by 410% and 177%, respectively. DFUs precede 85% of nontraumatic lower limb amputations,[2–5] with diabetes as the most common underlying cause of nontraumatic amputation in the United States and Europe.[3] When discussing

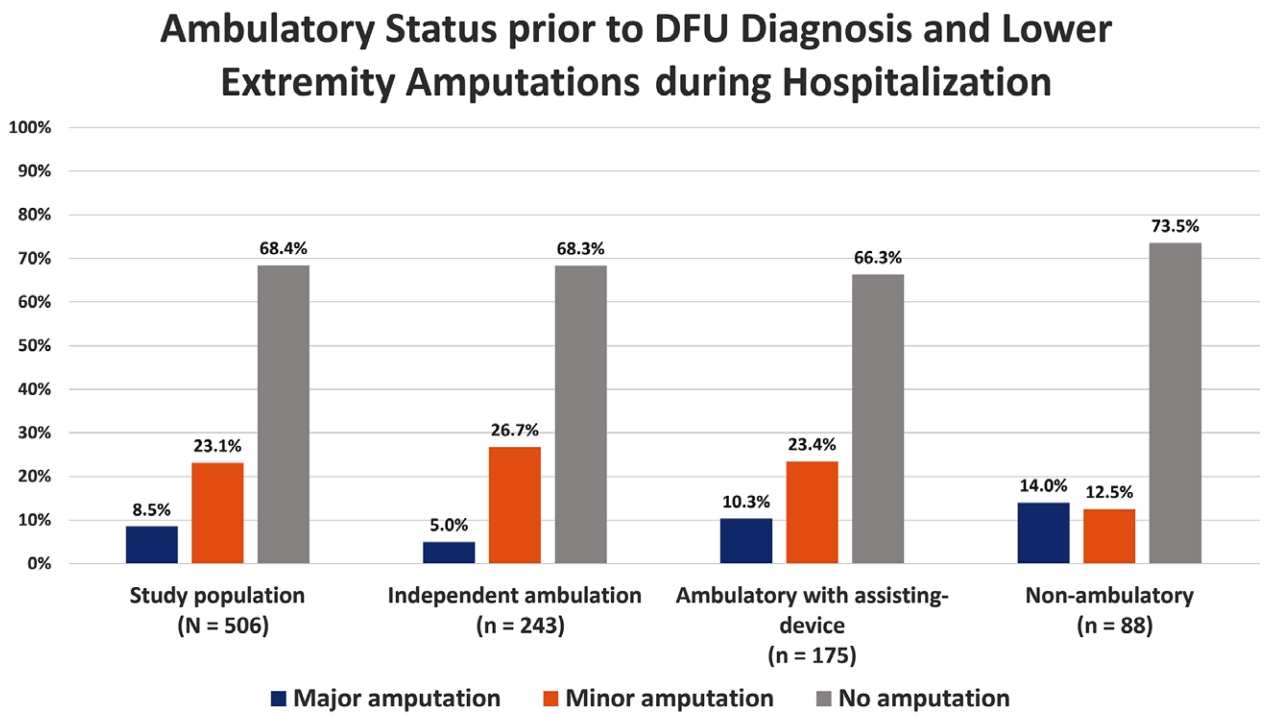

Fig. 1. The proportions of major (below or above-knee) and minor (toe or partial-foot) amputations during initial hospitalization among the study population and ambulatory status before DFU diagnosis groups.

ambulation in the diabetic population, it is important to consider factors that may be contributing to impairment. Peripheral neuropathy is present in more than 50% of diabetic patients older than 60 years, leading to the consequent vulnerability that increases the risk of foot ulceration sevenfold.[1] Additionally, excessive plantar pressure is associated with limited joint mobility, foot deformity, and gait imbalance that further perpetuates the mechanical stress causing wounds.[1,5] DFU prevention guidelines strongly suggest screening for limited joint mobility at regular intervals to decrease the likelihood of development.[9] These guidelines recommend foot and mobility-related exercises for gait and balance as well as an increase in walking-related weight-bearing activity that improves modifiable risk factors for foot ulceration, such as plantar pressure distribution, deficits in foot sensation, and foot-ankle joint mobility and strength.[9] A recent study found that neuropathic patients with chronic wounds requiring surgical intervention demonstrated poorer gait function in all parameters compared with nondiabetic controls, concluding that patients at risk of severe diabetic neuropathy should be further counseled to avoid greater ambulatory impairment.[23] Despite the well-recognized importance of regular mobility assessments in diabetic patients, ours is the first study to examine the utility of assessing ambulatory status before DFU diagnosis as an independent predictor of amputation and outcomes.

Within 30-days after DFU diagnosis, NA and AWAD status were associated with a 319% and 209% increase in the odds of ED visits, and AWAD status was associated with a 189% increase in the odds of hospital readmission. These findings highlight the financial burden of DFU treatment. The cost of annual diabetic foot care in the United States is approximately $46 billion, with one-third spent on DFUs alone.[15] The cost of care for these patients is 5.4 times higher in the year after the first ulcer episode.[16] Ambulatory status before DFU diagnosis may be used to identify patients that may require greater levels of surveillance and follow-up to avoid additional ED visits and hospitalizations.

When predicting any lower extremity amputation performed within 1 year of DFU diagnosis after initial hospitalization, AWAD status was significantly associated with a 73% increase in odds. Although NA status was not predictive of undergoing amputation within 1 year, this may be explained by the significantly higher proportion of NA patients who underwent major amputation during initial hospitalization or had died during the 1-year follow-up period. Patients who undergo amputation for DFU are at higher risk for additional amputations, with up to 20% of patients undergoing more proximal ipsilateral amputations or a contralateral amputation within 12 months, and up to 51% of diabetic amputees undergoing contralateral amputation within 5 years.[4,24,25]

When predicting all-cause mortality within 1 year of DFU diagnosis, NA and AWAD status were associated with a 319% and 209% increase in odds, respectively. These findings may be explained by the increased proportion of major amputations performed, older age, and the increased comorbidity burden in the impaired ambulation groups. Mortality after amputation ranges from 13% to 40% at one-year, 35% to 64% at 3 years, and 39% to 80% at 5 years.[1,3,10,11] After below-knee amputation (BKA), morality is approximately 25% within one-year and 40%–82% within 5 years, whereas after above-knee amputation (AKA) mortality is approximately 50% and 40%–90%, respectively.[10,11] Risk factors for mortality include increased age, renal disease, proximal amputation, and PVD.[3,10] Additionally, amputation can have a significant impact on cardiovascular dynamics and energy expenditure that can lead to further morbidity and deconditioning,[3,17] and may in part explain the significant predictive relationship found between impaired ambulatory status and mortality within 1 year. Although some patients can withstand major amputations and rehabilitate with a prosthesis, many are unsuccessful. Studies have demonstrated that less than half of patients reach functional prosthetic use after unilateral major lower-limb amputation.[12,13] The likelihood of ambulating with a prosthesis after BKA is 58%–65%, compared with 29%–33% after AKA, with many patients undergoing BKA ultimately converted to AKA.[11,13] One study found that after unilateral BKA, 45.5% of patients were wheelchair- or bedbound, whereas this proportion was 54.9% after AKA.[14]

The creation of multidisciplinary diabetic limb salvage (DLS) services has led to decreased amputation rates, with significant mortality benefit.[15–19] A recent systematic review found that these teams have reduced major amputations in 94% of studies.[19] Studies have reported high success rates, specifically with free tissue transfer, which had previously been avoided in this patient population before advancements in microsurgical technique and perioperative care.[15,19–21] One study reported an immediate success rate of 94%, with long-term success in 78.1% of patients.[15] Studies have also demonstrated that hospital length of stay and 30-day readmission rates were not increased, in addition to decreasing amputations.[18] Among DLS patients, 84%–86% achieved successful postoperative ambulation,[15,20,22] which demonstrates a promising improvement after traditional amputation.[15,26] A 2014 study examined the role of premorbid ambulation on the success of DLS, defined as a stump fit for functional ambulation, and found that a higher premorbid ambulation state increased the odds of a successful DLS operation.[26] This study is remarkable as the only one to assess the role of premorbid ambulation in limb salvage outcomes, but its significance remains unclear due to its unique DLS definition. When considering amputations in the diabetic population, they often have greater comorbidity and lower core strength, so they may benefit most from DLS to preserve limb length and improve survival.[27] The costs associated with amputation are well documented and support DLS efforts. Maintenance of an amputation stump and prosthesis along with other associated healthcare problems can result in far greater costs than the initial costs of DLS.[2,16] Limb salvage may preserve quality of life in addition to minimizing the risk of deconditioning seen with amputation.[3,17]

This study's limitations include its retrospective nature. As most included patients identify as White, these findings may not be generalizable to all populations. Due to the retrospective nature of this study and the heterogeneity of reporting by patients and providers, we were unable to control for the length of time a DFU was present before diagnosis during initial hospital encounter, or the exact location of the ulcer on the foot, and we were unable to assign a standardized classification system with reliability. Although our statistical models included covariates such as age, sex, race, and multiple comorbidities that are known to increase the risk of DFU, amputation, and poor outcomes, we are unable to control for all potential confounding variables. We are also unable to account for surgeon equipoise and patient preference during treatment, which may have resulted in the bias toward a greater number of NA patients undergoing amputation to potentially avoid multiple surgical procedures. Our center does not currently have a multidisciplinary DLS service, but does offer comprehensive care with endocrinologists, podiatrists, orthopedic and vascular surgeons, and plastic surgeons offering all microsurgical reconstruction options. Additional larger, prospective studies are needed to determine if screening for ambulatory status before DFU diagnosis can be used to intervene in those patients who are most at risk for poor outcomes, as well as determine its utility in predicting outcomes of DLS compared with amputation.

CONCLUSIONS

Impaired ambulation (NA and AWAD) was predictive of major amputation during hospitalization and poorer 1-year outcomes, including mortality. With the increasing prevalence of diabetes and associated foot ulcers, assessment of prior ambulatory function before DFU diagnosis may be an effective tool for delineating patients that are at higher risk for amputation and poor outcomes within 1 year. These findings may be able to provide treating physicians and patients with more prognostic information, as well as allow limb salvage teams to identify patients that may benefit the most from lower extremity reconstruction instead of amputation.

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DISCLOSURE

The authors have no financial interest to declare in relation to the content of this article.

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